

EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

acc. to Directive 93/42/EEC on Medical Devices

Name and Address of the Manufacturer: Maquet Critical Care AB
Röntgenvägen 2
SE-171 54 Solna, Sweden

On our sole responsibility, we hereby declare that the product(s)

Product Description: Anesthesia System

Product Identification: Flow-c Anesthesia System,
System version 4.7

Product-No.: See Annex I of this document

Classification (acc. to Annex IX of MDD): Class IIb

comply with the relevant provisions of the following Directive(s):

Directive 93/42/EEC on Medical Devices

Notified Body: TÜV SÜD Product Service GmbH
ID No. 0123
Zertifizierstelle, Ridlerstraße 65
80339 München, Germany
Conformity Assessment Procedure: acc. to Annex II excluding (4) of Directive 93/42/EEC

Directive 2011/65/EU on the restriction of the use of certain substances in electrical and electronic equipment

This declaration is valid until the next change of the product or until the expiration date of the Certificate (No. G1 072017 0014, **dated 2020-01-22**, valid to **2024-05-26**) issued by the notified body. Any modification of the medical device not authorized by us will invalidate this declaration.

For the signature of the Manager for Product Compliance on behalf of Maquet Critical Care AB see left corner of page.

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2020-04-21 10:14 by Jerker Åberg u2773956

ANNEX I TO THE EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Product(s) Covered:

Trade Name	Article No.
Base unit	
Flow-c Anesthesia System	6887700
Additional ventilation modes	
PRVC	6688202
PS with backup	6688200
SIMV (VC) and SIMV (PC)	6688197
Pressure Control	6888006
Low VT ventilation	6887892
High performance ventilation	6887889
Additional options	
HLM/CBP	6887895
Insp hold/Exp hold	6887896
Predicted body weight (PBW)	6887893
Agent usage	6887888
Optional module, Additional Fresh Gas Outlet (AFGO)	6681887
AFGO adapter kit, onsite upgrade	6887999
AFGO adapter kit	6887704
Absorber	
CO2 Absorber Disposable	6677845
CO2 Absorber disposable 12 pcs	6887738
CO2 Absorber Reusable	6692582

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Dust Filter for CO2 Absorber Reusable	6880430
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Vaporizer

Vaporizer Sevoflurane, QUIK FIL	6682285
Vaporizer Desflurane, Saf-T-Fil	6682287
Vaporizer Isoflurane, Maquet filling	6682280
Vaporizer Sevoflurane, Maquet filling (Abbott, Baxter)	6682282
Vaporizer Sevoflurane Maquet filling	6886601
Vaporizer Sevoflurane QUIK FIL	6886611
Vaporizer Isoflurane Maquet filling	6886621
Vaporizer Desflurane SAF-FIL	6886631
Vaporizer Sevoflurane SAFE-T-SEAL	6887135
Vaporizer Sevoflurane SAFE-T-SEAL	6887523
MAQUET filling adapter tube for isoflurane bottle	6682290
MAQUET filling adapter tube for sevoflurane bottle (Abbott, Baxter)	6682292
Cover for Vaporizer Slot	6880158
Vaporizer Holder	6880155

O2 flowmeter / suction equipment

External suction vacuum	6887709
Venturi for Suction	6887710
Hydrofobic Bacterial Filter (5 pcs)	6887498

Backup gas supply

Backup gas rack O2, Pin index	6887416
Backup gas rack Air, Pin index	6887417

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Backup gas rack N ₂ O, Pin index	6887418
Connector DIN 6	6886811
Connector DIN 9	6886812
Connector DIN 12	6886813
Connector DIN 13	6886814

EVAC outlet Connections

EVAC Restrictor	6880156
22 mm out. Diam. Connector	6692740
30 mm out. Diam. ISO taper connection	6673980
12.7 mm/1/2" in house Barb connector	6679627
25 mm/1" in house Barb connector	6679630
AGA EVAC connector	6679645
WAGD-to-Vacuum connector	6692742
Connection tube 22 int. diam, (disposable), 50 m	6189646
DISS EVAC connector	6679647

Gas analyzer parts

Water trap Dryline A, 10 pcs	6522747
Water trap Dryline 1, 10 pcs	6889352

Extra breathing system parts

Patient cassette complete, extra	6680325
Volume reflector, extra	6887614

Reusable parts

Tube joint/adaptor 22 mm	6425581
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ANNEX I

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FOR MEDICAL DEVICES

Hardware mounting kits

Flexible Man bag arm	6887717
Tubing hook small	6887713
Tubing hook large	6887712
Suction tip holder	6887714
Hook and y-piece holder	6880548
Cable holder	6693747
Lockable compartment for drawer	6887718
Additional table	6676962
Hook and hook holder	9368952
Clamp, 1 slot	9358193
Horizontal short rail DIN	6887115
Horizontal short rail Duoflex	6887834
Clamp, for Duoflex rail, 10 x30 mm	6038819
Clamp, for DIN rails, 10 x 25 mm	6038801
Monitor arm 2 pin (Philips)	6887066
Panel interface Height adjustable	6886960
Long divider for big drawer	6886664

For upgrade of installed Flow-c

Upgrade via freight, Flow-c	6888360
Upgrade via E-delivery, Flow-c	6888359

Cleaning adapter

Cleaning adapter kit	6681910
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